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PK 7276 17 July 1991 (17.07.91) AU(71) Applicant (for all designated States except US): LONSTEN
PTY. LIMITED [AU/AU]; 50 Miller Street, North Syd-
ney, NSW 2060 (AU).

(72) Inventors; and

(75) Inventors/Applicants (for US only) : STENNING, Henry,
Martin [AU/AU]; 42 Prince Albert Street, Mosman,
NSW 2088 (AU). LONDISH, Sidney [AU/AU]; Level 3,
50 Miller Street, North Sydney, NSW 2060 (AU).(74) Agent: HEATHCOTE, Peter, Rex; Shelston Waters, 55
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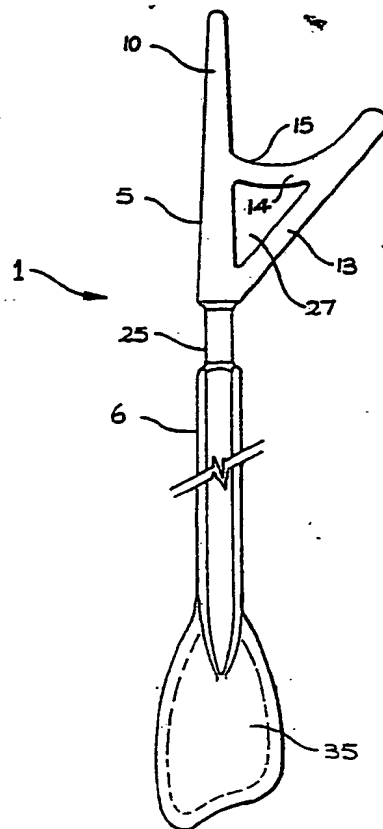
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(54) Title: PAP SMEAR SAMPLING DEVICE

(57) Abstract

A pap smear sampling device (1) for use in the detection of cancer cells in the female cervix (2), said device including a sampling head (5) adapted to engage and scrape the surface of the cervix for collection of sample cells. An elongate handle (6) permits remote rotation and manipulation of the sampling head, which further comprises a probing stem (10) extending generally axially from the handle for insertion into the cervix to collect sample cells from the endocervix. A relatively rigid support portion (13) extends outwardly from the handle or the stem, and a relatively flexible web portion (14) extends generally intermediate the stem and the support portion to define a flexible wiping blade (15) adapted to scrape and collect sample cells from the ectocervix. The blade (15) is adapted flexibly to conform closely to the surface contours of the ectocervix, whilst maintaining an effective scraping angle upon said rotation and manipulation of the sampling head.



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Title: PAP SMEAR SAMPLING DEVICE

TECHNICAL FIELD

The present invention relates to pap smear sampling devices of the type used in the gynaecological field for the detection of cancer cells in the female cervix.

BACKGROUND ART

A number of sampling devices have hitherto been available to conduct these so-called "pap smear" tests. Such devices are generally adapted to be inserted into the cervix and then rotated so as to wipe or scrape the surface of the cervix, in an attempt to collect and retain sample cells. Once the sample has been taken, at least a proportion of the cells collected on the sampler are transferred to a glass optical slide for subsequent examination under a suitable microscope, in an attempt to ascertain the cancer status of the cervix. This procedure is well known and understood by those skilled

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in the art, and so will not be described in more detail here.

It has been found in practice, however, that known pap smear sampling devices are inadequate in a number of significant respects. It has been shown statistically that the accuracy of cervical cancer detection is relatively low, and many cases go undetected in the early stages, largely as a result of the inefficiency of the pap smear sampling devices currently in use.

One known type of sampling device is formed from wood and incorporates a sampling head corresponding generally to the cross sectional surface profile of the cervix. However, such "spatula" type devices are excessively rigid, and so are not well adapted to properly accommodate the wide variations in size and shape of cervix which are routinely encountered. Moreover, because of the inability of these rigid spatulas to conform flexibility to the relatively complex and varied surface contours of the cervix, the effective area of coverage during the sampling procedure is relatively small. This in turn can lead to inaccurate diagnosis, and can also cause excessive pain and discomfort to the patient. The spatula type samplers also have a tendency to cause contact bleeding, which makes detection of cancer cells amongst the interspersed red blood cells considerably more difficult and less accurate.

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In an attempt to ameliorate these problems, a number of prior art devices have incorporated various configurations of bristles, fibres, filaments or brushes, which are generally mounted on a support arm or wire. However, these "brush" type devices can also cause substantial pain and bleeding, as well as damage to the cervical sample, particularly if sufficient care is not taken during the sampling procedure. Such samplers do tend to give better surface coverage than the rigid spatula type devices discussed above, by virtue of the fact that the bristles can resiliently deform to a certain extent, thereby enabling the brush to conform more closely to the surface contours of the cervix. However, these devices still cannot provide complete coverage, and in addition suffer the inherent problem of poor transfer- ability of the collected sample to the microscope slide for subsequent analysis. This is largely because the sample cells tend to remain trapped in the interstitial voids between the bristles within the inner confines of the brush, and are therefore not readily accessible and transferable to the slides. Again, this leads to inaccurate diagnosis, particularly in the critical preliminary stages of cervical cancer.

Moreover, with both the major types of known samplers discussed above, the cancer cells and dysplastic cells are often damaged or deformed during

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the sampling procedure, and so become more difficult to detect accurately with known diagnostic techniques. Combined with the inherent inadequacies of the sampling devices in terms of poor coverage and inadequate sample transfer, this reduces even further the accuracy of the pap smear test in terms of its ability to provide a reliable indication of cervical cancer.

Finally, many known sampling devices tend not to be able to differentiate effectively between the inside and outside sample areas of the cervix, and so are not effective in isolating sample cells collected from the endocervix and ectocervix respectively, which is also important for accurate diagnosis.

It is therefore an object of the present invention to provide an improved pap smear sampling device which overcomes or substantially ameliorates at least some of the disadvantages of the prior art.

DISCLOSURE OF THE INVENTION

Accordingly, the invention provides a pap smear sampling device for use in the detection of cancer cells in the female cervix, said device including a sampling head adapted to engage and scrape the surface of the cervix for collection of sample cells, and an elongate handle to permit remote rotation and manipulation of the sampling head, said sampling head comprising a probing stem extending generally axially from the handle for insertion into the cervix to collect sample cells from

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the endocervix, a relatively rigid support portion extending outwardly from the handle or the stem, and a relatively flexible web portion extending generally intermediate the stem and the support portion to define a flexible wiping blade adapted to scrape and collect sample cells from the ectocervix, said blade being adapted flexibly to conform closely to the surface contours of the ectocervix, whilst maintaining an effective scraping angle upon said rotation and manipulation of the sampling head.

Preferably, the probing stem includes at least one longitudinally extending rib adapted rotatingly to scrape sample cells from the endocervix, and at least one corresponding longitudinally extending recessed channel or groove disposed adjacent the rib to retain the sample cells scraped from the endocervix by the rib. In another embodiment, the stem takes the form of a relatively flat narrow blade generally rectangular in transverse cross section, in which case the sample is simply retained on the flat faces of the stem.

Preferably also, the device includes a relatively flexible joint disposed intermediate the handle and the sampling head to permit a degree of relative axial movement therebetween. This enables effective rotation and manipulation of the device with the handle inclined at an oblique angle with respect to the head. In the preferred embodiment, the flexible joint is conveniently

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provided by an intermediate neck region of reduced cross sectional area immediately adjacent the sampling head.

Preferably also, the sampling head is formed substantially from a suitable elastomeric material such as rubber, santoprene, silicon, flexible polyurethane, or the like.

In one embodiment, the sampling head includes a second support arm effectively interconnected with the first, and extending axially within the probing stem to facilitate insertion into and location within the cervix. The first and second support arms are preferably formed from spring steel wire or plastic, and are connected to the handle for releasable detachment from a separate elastomeric portion of the sampling head incorporating the flexible web. In other embodiments, the support arms may be integrally moulded within a surrounding elastomeric portion, to form a composite sampling head of unitary construction.

In the preferred embodiment, however, the sampler is formed from one type of material in a single moulding and the difference in flexibility between the wiping blade and the support portion is achieved by an appropriate variation in material thickness.

BRIEF DESCRIPTION OF DRAWINGS

Preferred embodiments of the invention will now be described, by way of example only, with reference to the accompany drawings in which:

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Figure 1 is a side elevation showing a first embodiment of a pap smear sampling device according to the invention;

Figure 2 is a cross-sectional view taken along line 2-2 of Figure 1;

Figure 3 is a diagrammatic side elevation showing the device of Figure 1 in position ready for use adjacent a cervix;

Figure 4 is a side elevation similar to Figure 1 showing the sampling head of a second embodiment of the invention;

Figure 5 shows a third embodiment of the invention;

Figure 6 shows a fourth embodiment;

Figure 7 is a front elevation showing a further embodiment of the invention, formed from a single material;

Figure 8 is a side elevation of the sampler of Figure 7 showing the variation in thickness between the wiping blade and the support arm; and

Figure 9 shows an alternative form of flexible neck disposed intermediate the sampling head and the handle.

BEST MODE FOR CARRYING OUT THE INVENTION

Referring firstly to Figures 1 to 3, the invention provides a pap smear sampling device 1 for use in the detection of cancer cells in the female cervix 2 in accordance with the established gynaecological "pap smear" testing procedure well known and understood by

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those skilled in the art. The sampling device includes a sampling head 5 adapted to engage and scrape the surface of the cervix for collection of sample cells, and an elongate handle 6 to permit remote rotation and manipulation of the sampling head when engaged with the cervix.

The sampling head 5 comprises a relatively firm probing stem 10 extending generally axially from the handle 6 for insertion into the cervix to collect sample cells from the endocervix 12. The sampling head further includes a first outwardly extending relatively rigid support arm 13 formed from spring steel wire, plastics or other suitable material. A relatively soft flexible web 14 extends intermediate the stem 10 and the remote end of the first support arm 13 to define a flexible wiping blade 15 adapted to scrape and collect sample cells from the ectocervix 16. The flexibility of the web 14 enables the marginal edge of the wiping blade 15 flexibly to conform closely to the complex surface contours of the ectocervix, whilst the relatively rigid support provided by first arm 13 enables an effective scraping angle relative to the cervix to be maintained, upon rotation and manipulation of the device. The sampling head preferably includes a second support arm 17 interconnected with the first arm 13 to provide relatively rigid internal support for the stem, thereby facilitating insertion into and positive location within

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the cervix.

The stem 10 includes a longitudinally extending protruding rib 20 adapted to scrape the endocervix upon rotation of the sampling head, and a pair of corresponding longitudinally extending recessed channels 21 disposed on either side of the rib to retain the sample cells scraped from the endocervix by the rib, upon withdrawal of the sampling device.

The handle 6 immediately adjacent the sampling head includes a neck region of reduced cross-sectional area forming a flexible "universal" joint 25. The joint 25 permits a limited degree of relative movement and axial misalignment between the handle and the sampling head. This facility enables effective rotation and manipulation of the sampling head with the handle inclined at an angle with respect thereto. Other forms of flexible joint are also envisaged.

In the embodiment of Figures 1 to 3, the relatively soft and flexible portion of the sampling head including the probing stem and transverse web is preferably moulded from a suitable elastomeric material such as rubber, santoprene, silicone, flexible polyurethane, polypropylene, polyethylene or the like. The support arms 13 and 17 are preferable formed from spring steel wire, although it will be appreciated that any suitably firm or relatively rigid metal, plastics, polymer, wood or other material can also be used.

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A second embodiment of the invention is shown in Figure 4, wherein corresponding features are denoted by corresponding reference numerals. In this embodiment, the central and lower portion of the web 14 is removed, effectively to define cut-out region 27. This configuration provides greater flexibility for the wiping blade 15, and thereby reduces the axial force required for the blade to conform closely to the complex outer surface contours of the ectocervix during the sampling procedure. This configuration also saves on material costs. It should be appreciated, however, that in this embodiment, the transverse web 14 is still provided with sufficient frontal area to retain the collected cell sample, below the operative marginal edge of the wiping blade. A similar form of the invention is shown in Figure 6.

In the embodiments of Figures 1, 4 and 6, the elastomeric portion 28 of the sampling head is formed in a separate moulding step, and is releasably detachable from the complementary support arms 13 and 17 which are fixedly connected with the handle. In this way, the design provides for the substitution of interchangeable elastomeric head portions 28 of different size, shape, or resiliency, to suit particular applications. Thus, a range of interchangeable elastomeric head portions can be provided to enable the sampling device to be tailored to suit individual patients' requirements.

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A third embodiment of the invention is shown in Figure 5, where again, corresponding features are denoted by corresponding reference numerals. In this embodiment, the elastomeric material is actually moulded around an internal wire support frame, consisting essentially of the first and second support arms 13 and 17. The composite sampling head is then attached as a unitary structure to a complementary handle by means of elastomeric boss portion 30, which is captively retained within a complementary socket formed in the handle (not shown).

Figures 7 and 8 show a fourth embodiment of the invention. In this case, there is no separate support frame formed from spring steel wire or other material. Rather, the entire sampler is formed from a single suitably flexible material such as polyethylene, or polypropylene as a one piece moulding. There is, however, still a difference in relative flexibility between the wiping blade 15 and associated support arm 13 which, as best seen in Figure 8, is achieved by a difference in material thickness rather than material type. More particularly, the web portion 14 defining the scraping blade is relatively thin and correspondingly flexible, thereby enabling it to resiliently deform to accommodate irregularities in the surface profile of the ectocervix during sampling. On the other hand, the support portion 13 is relatively

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thick in transverse cross section particularly adjacent its base, thereby to provide a relatively rigid support for the remote end of the wiping blade.

In this embodiment, cut-out region 27 is provided to enhance flexibility of the wiping blade and economise on material. It should be appreciated, however, that this portion could be "filled-in" so as to form a gusset extending between the remote end of the wiping blade and the base of the sampling head. This would function in a mechanically analogous way. However, instead of a discrete support arm separate from the web, there is simply a smooth transition from the relatively thick support section of the gusset adjacent the base of the sampling head, to the relatively thin and flexible operative edge of the scraping blade. Further, the endocervical probe portion does not incorporate discrete ribs and channels, but rather has a simple rectangular cross-sectional configuration, which has also been found to be effective in collecting cells from the endocervix.

This embodiment also incorporates an additional sampling member 35 disposed on the terminal end of the handle remote from the head, for use in applications not requiring penetration of the probing stem.

In each case, the operative edge of the wiping blade is adapted to curve through an angle of between around 90° to 180° and preferably around 140° from the stem. That is to say, a tangent projected from the

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remote tip of the operative edge of the wiping blade intersects a projected axis of the stem and handle at an included angle of between around 0° to 90° , and preferably around 40° . This extent of curvature ensures adequate coverage of the ectocervix, and is only able to be effectively achieved by virtue of the support afforded to the remote end of the wiping blade by the support portion.

Turning now to describe briefly the method of use, the sampling device is first positioned in the conventional manner and the probing stem 10 inserted into the cervix, thereby radially locating the sampling head. The device is then manually rotated by the handle (in either the clockwise or anticlockwise direction). In this way, the endocervix is scraped by longitudinal rib 20 whereby sample cells are collected and retained within the recessed channels 21. In the case of the embodiment of Figures 7 and 8, the endocervical cells are simply retained on the flat faces of the probe. Simultaneously, the wiping blade 15 defined by flexible web portion 14 scrapes the entire outer surface of the ectocervix, whereby sample cells are collected and retained on the frontal surface of the web. During this operation, as a result of axial pressure applied by the operator, the wiping blade flexibly and progressively conforms to the complex profiles of the cervix, including any surface irregularities. At the same time,

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the support arm or section 13 maintains an effective scraping angle over the entire cervix by providing support for the end of the wiping blade remote from the stem and thereby permitting substantially uniform pressure distribution across the blade. In this way, sample cells are recovered from substantially the entire outer surface of the cervix. It will be appreciated that the relative flexibility of the web intermediate the support portion and stem maximises the effective sampling area, whilst minimising contact bleeding and patient discomfort. This is in contrast with prior art devices, which have generally been unable to effectively wipe the entire ectocervix, because of the lack of flexible form-fitting capability and/or the lack of support for the remote end of the wiping which prevents sufficient pressure to be applied uniformly across its operative edge.

Once the sampling procedure has been completed, the device is withdrawn. The samples from the stem 10 and web 14, containing cells collected from the endocervix and ectocervix respectively, are then transferred by a simple wiping action onto an appropriate optical slide for subsequent analysis and testing in accordance with established diagnostic procedures.

During transfer of the sample from the stem to the slide, in the embodiments shown in Figures 1 to 6, sufficient wiping pressure is applied against the slide

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to fold back the rib 20 so that the full sample retained within the channels 21 is exposed and progressively transferred by the wiping action onto the slide. Similarly, a simple wiping action is sufficient to transfer the entire sample from the frontal face of the web 14 to the slide. This operation is also facilitated by the support afforded to the web by the support portion 13. Consequently, substantially the entire sample is available for analysis.

In other embodiments (not shown), the web 14 may include a series of spaced apart slits extending generally parallel to the stem, whereby the marginal edge of the wiping blade 15 is still effectively continuous, but defined by a series of complementary wiping "fingers". It is envisaged that this will further enhance the ability of the wiping blade to conform closely to irregular surface contours of the cervix, whilst still providing excellent coverage over substantially the entire outer surface of the cervix and substantially complete transferability of the sample to a slide.

It will be apparent that the present invention provides a number of significant advantages over the prior art. Firstly, as a result of its inherent "form-fitting" capability, the effective area of coverage during the sampling procedure for a given length of wiping blade is greatly increased,

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particularly when compared with the rigid prior art "spatula" type devices. Moreover, the support provided for the remote end of the wiping blade enables it to wrap further around the ectocervix than flexible prior art samplers, and still support sufficient scraping pressure to consistently recover a complete sample. Furthermore, the device according to the present invention enables virtually complete transfer of the collected sample to a microscope slide for subsequent analysis. There is no possibility of sample cells remaining trapped in interstitial voids between bristles fibres, or filaments as occurs with prior art "brush" type devices. As previously mentioned, on a statistical basis this significantly reduces the probability of inaccurate diagnosis. Additionally, the flexible joint provided intermediate the sampling head and the handle enables the device to accommodate a significant degree of operator error, by virtue of the fact that the sampling head is adapted automatically to assume the optimum position around the cervix, despite relative axial misalignment of the handle within a reasonably broad range of tolerance.

The improved configuration and flexibility of the sampling head thus enables the device to accommodate a wide variation in cervix size and shape, whilst affording precise control and minimising pain, discomfort, bleeding, and cell damage. By reducing

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contact bleeding and cell damage, the likelihood of inaccurate diagnosis of the cancer status of the cervix is significantly reduced. Sampling time is also significantly reduced because the device is able to provide an effective and accurate "first time" sample.

The accuracy and specificity of the diagnosis is further enhanced by enabling distinct inside and outside cervix samples to be taken simultaneously, and subsequently isolated on separate slides for individual analysis if required. More particularly, because the sample is transferable by a straight wiping action, the relative transverse position of any cancer cells detected on the slide can be approximately correlated to a corresponding position on the surface of the cervix, thereby providing a relatively accurate target zone for subsequent testing. This is in contrast with prior art sampling devices, which require the sample to be transferred to a slide by a random brushing, scraping or spreading action which effectively destroys any meaningful correlation between the relative positions of sample cells on the slide. Thus, it will be apparent that the present invention represents a commercially significant improvement over the prior art.

Although the invention has been described with reference to specific examples, it will be appreciated by those skilled in the art that the invention may be embodied in many other forms. For example, the probe

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need not incorporate a longitudinally extending rib and channel as described, but may incorporate a series of longitudinal ridges, recessed grooves, surface dimples, or be of any other suitable non-circular cross-sectional profile.

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CLAIMS:-

1. A pap smear sampling device for use in the detection of cancer cells in the female cervix, said device including a sampling head adapted to engage and scrape the surface of the cervix for collection of sample cells, and an elongate handle to permit remote rotation and manipulation of the sampling head, said sampling head comprising a probing stem extending generally axially from the handle for insertion into the cervix to collect sample cells from the endocervix, a relatively rigid support portion extending outwardly from the handle or the stem, and a relatively flexible web portion extending generally intermediate the stem and the support portion to define a flexible wiping blade adapted to scrape and collect sample cells from the ectocervix, said blade being adapted flexibly to conform closely to the surface contours of the ectocervix, whilst maintaining an effective scraping angle upon said rotation and manipulation of the sampling head.
2. A sampling device according to claim 1 wherein said wiping blade defines a substantially smooth effectively continuous operative edge adapted for engagement with the ectocervix.
3. A sampling device according to claim 1 or claim 2 wherein the wiping blade includes a series of spaced apart slits extending generally parallel to the stem to

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define a corresponding plurality of wiping fingers.

4. A sampling device according to any one of the preceding claims wherein the support portion comprises a first support arm, and further including a second support arm effectively interconnected with the first, the second support arm extending axially within the stem.

5. A sampling device according to claim 4 wherein the first and second support arms support a separate elastomeric head portion incorporating the flexible web.

6. A sampling device according to claim 5 wherein the elastomeric head portion incorporating the flexible web is interchangeable with corresponding head portions of different size, shape, or material properties to suit particular applications.

7. A sampling device according to claim 4 wherein the support arms are integrally moulded within a surrounding elastomeric head portion incorporating the flexible web, to form a composite sampling head of unitary construction.

8. A sampling device according to any one of claims 4 to 7 wherein the support arms are formed from a metallic wire and the surrounding elastomeric head portion is formed from a suitable plastics material or rubber.

9. A sampling device according to any one of claims 1 to 7, wherein the sampling head is formed substantially from a single type of material and wherein the difference in flexibility between the wiping blade and

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the support portion is achieved by an appropriate variation in material shape, configuration, thickness or cross sectional area.

10. A sampling device according to claim 9, formed from a singled material in a one-piece moulding.

11. A sampling device according to any one of the preceding claims, wherein the sampling head incorporates a cut-out region disposed generally intermediate the wiping blade and the support portion.

12. A sampling device according to any one of claims 1 to 10 wherein the region generally intermediate the wiping blade, the support portion and the stem is filled-in with additional support material to form a support gusset for the wiping blade.

13. A sampling device according to any one of the preceding claims, wherein the stem includes at least one longitudinally extending rib adapted rotatingly to scrape sample cells from the endocervix.

14. A sampling device according to claim 13, wherein the stem further includes at least one corresponding longitudinally extending channel or groove disposed adjacent the rib to retain sample cells scraped from the endocervix.

15. A sampling device according to any one of the preceding claims, wherein the stem is generally flat, and substantially rectangular in transverse cross section.

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16. A sampling device according to any one of the preceding claims, further including a relatively flexible joint disposed intermediate the handle and the sampling head to accommodate a degree of relative axial misalignment therebetween, and thereby enable effective rotation and manipulation of the device with the handle inclined at an oblique angle with respect to the head.

17. A sampling device according to claim 16 wherein the flexible joint is defined by an intermediate neck region of reduced cross-sectional area, providing increased flexibility relative to the handle and the head.

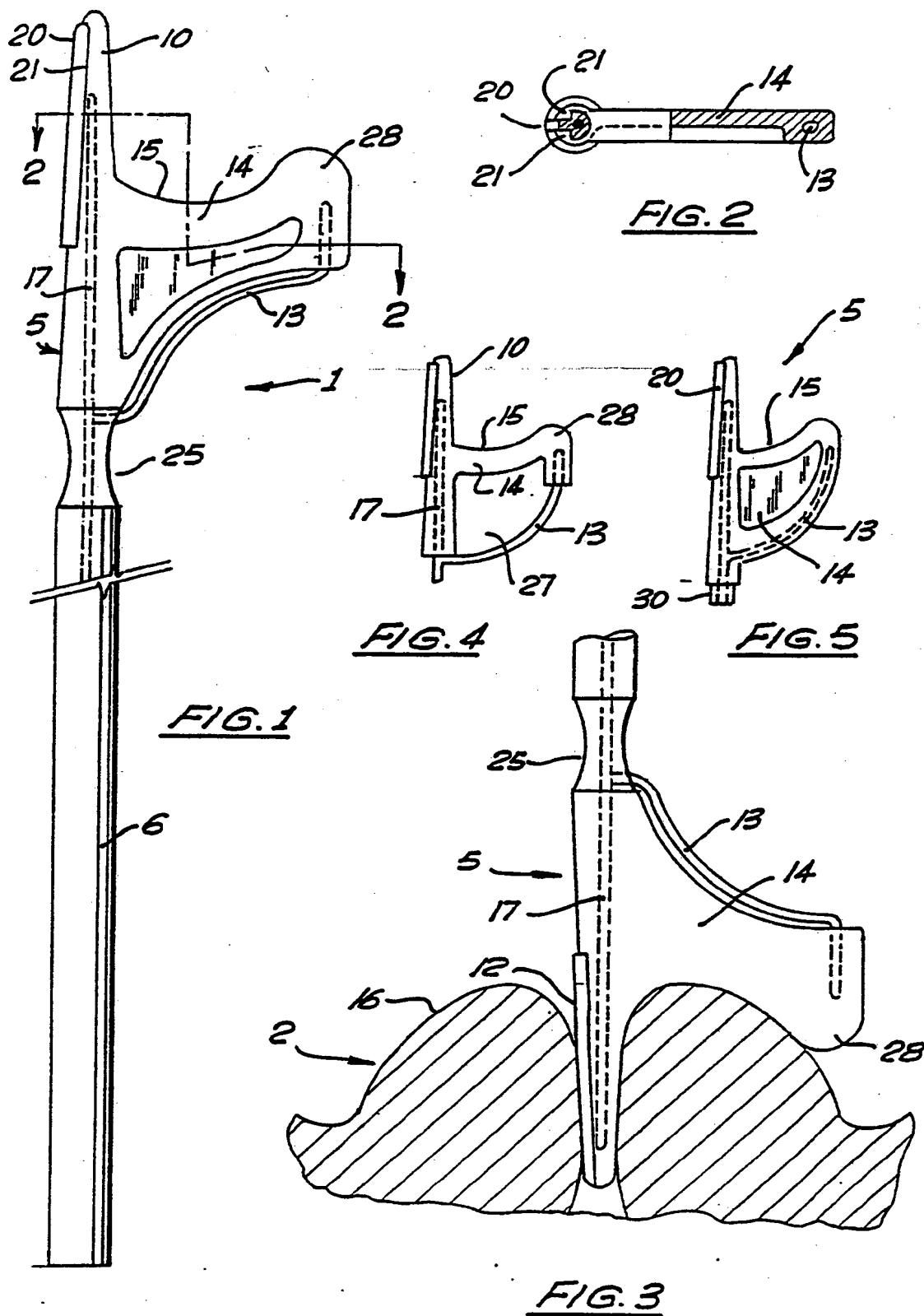
18. A sampling device according to claim 16 or 17 wherein the sampling head is adapted automatically to tend to assume an optimum orientation for scraping around the cervix, within a limited range of relative axial misalignment with respect to the handle.

19. A sampling device according to any one of the preceding claims, further including an additional sampling member disposed on the terminal end of the handle remote from the head, the additional sampling member being adapted to scrape sample cells from the ectocervix, in applications not requiring penetration of the endocervix by the probing stem.

20. A sampling device according to any one of the preceding claims wherein the wiping blade is adapted to extend around substantially the entire outer surface of the ectocervix.

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21. A sampling device according to claim 19 wherein the remote edge of the wiping blade is inclined tangentially at an angle of between around 0° to 90° to a generally longitudinal axis of the handle and the probing stem.
22. A sampling device according to claim 21 wherein the remote end of the wiping blade is inclined tangentially at an angle of around 40° .
23. A sampling device according to any one of the preceding claims, formed from a suitable material selected from the group comprising rubber, santoprene, silicon, polyurethane, polyethylene, and polypropylene.



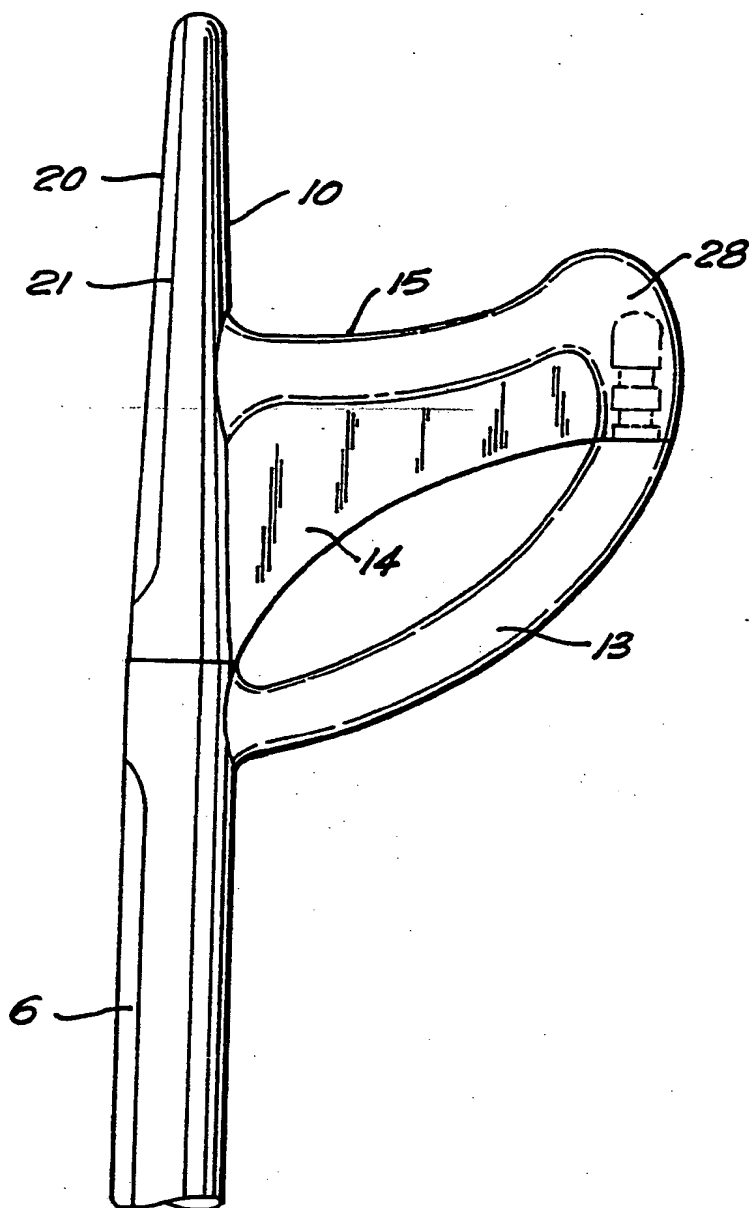


FIG. 6

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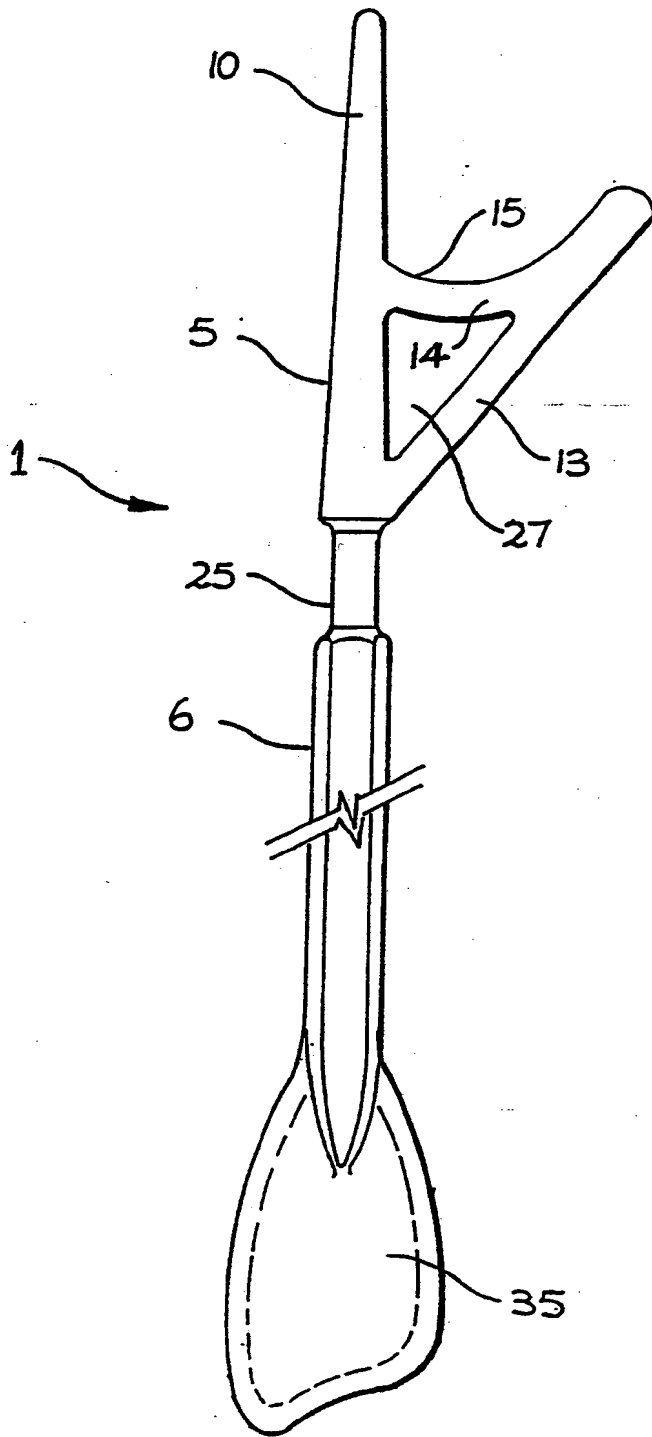


FIG. 7

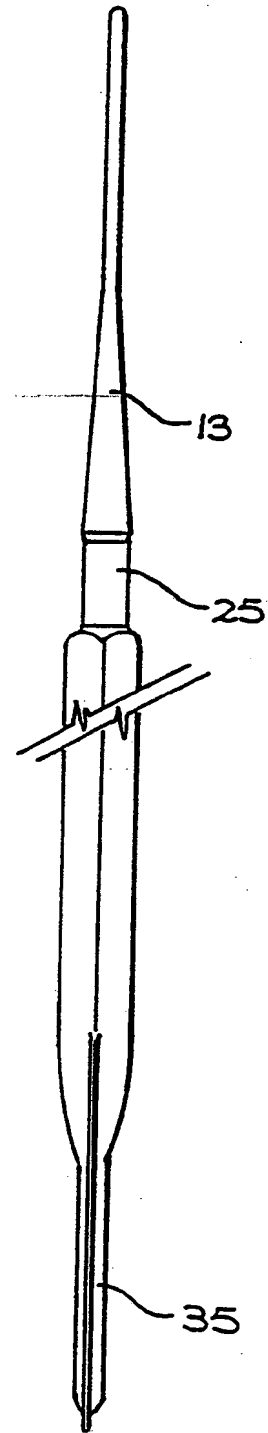


FIG. 8

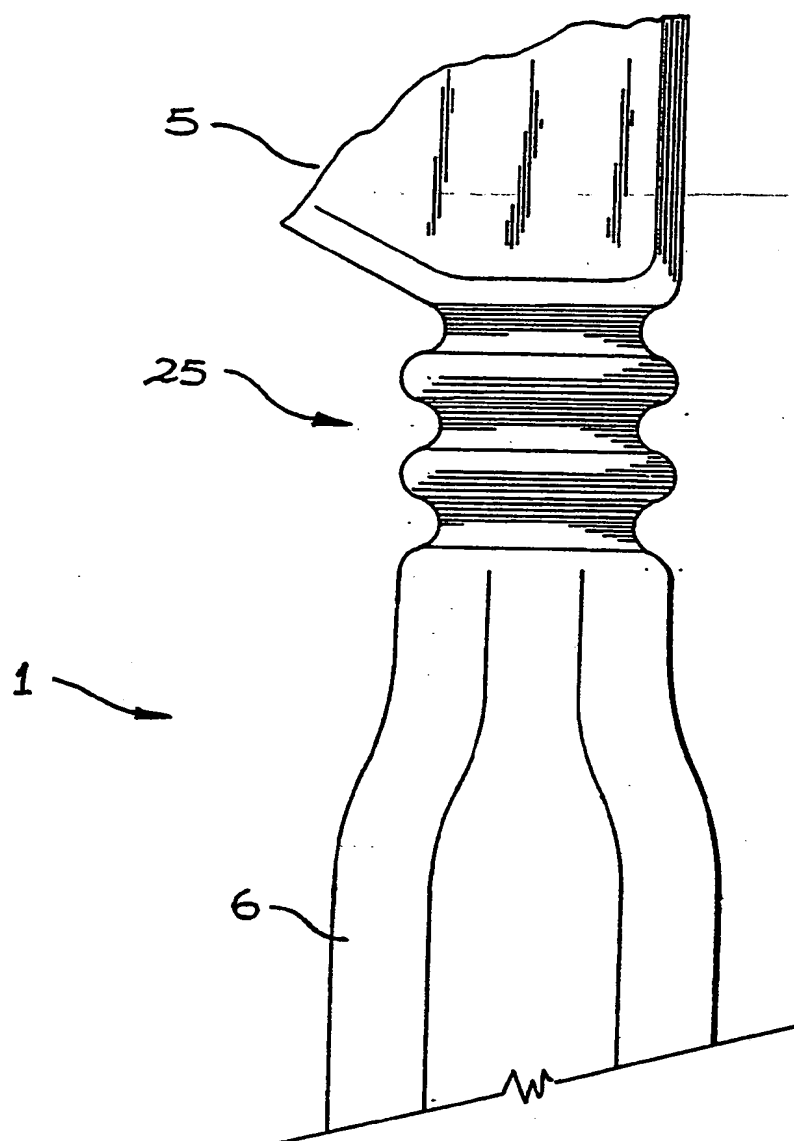


FIG. 9

A. CLASSIFICATION OF SUBJECT MATTERInt. Cl.⁵ a61b 10/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC A61B 10/00

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
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DERWENT
JAPIO**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to Claim No.
P,X	EP, A, 448137 (VAN DOOREN) 25 September 1991 (25.09.91). Column 3 lines 35-46.	1
P,X	WO, A, 91/16855 (MEDSCAND AB) 14 November 1991 (14.11.91). Page 6 lines 3-32, page 7 line 30-page 8 line 6 Figures 6, 7.	1, 11, 16-18, 20-23
A	US, A, 4016865 (FREDRICKS) 12 April 1977 (12.04.77). Whole document.	
A	EP, A, 235673 (GRAF) 9 September 1987 (09.09.87). Whole document.	

☒ Further documents are listed
in the continuation of Box C.☒ See patent family annex.

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Date of the actual completion of the international search
23 September 1992 (23.09.92)

Date of mailing of the international search report

14 Oct 1992 (14.10.92)

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Category *	Citation of document, with indication, where appropriate of the relevant passages	Relevant to Claim No.
A	GB, A, 892548 (SHUTE) 28 March 1962 (28.03.62). Whole of document.	
A	GB, A, 1408140 (LEVENE) 1 October 1975 (01.10.75). Whole document.	

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report				Patent Family Member			
EP	448137	NL	9000166	US	5131402		
WO	91/16855	AU	78845/91	SE	9001679		
EP	235673	CH	669103				
GB	1408140	DE	2259582	JP	48-065792	US	3881464